

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY)	MDL No. 1456
AVERAGE WHOLESALE PRICE LITIGATION)	Master File No. 01- 12257-PBS
)	Subcategory Case. No. 06-11337
)	
)	Hon. Patti B. Saris
THIS DOCUMENT RELATES TO:)	
)	Magistrate Judge
<i>United States of America ex rel. Ven-A-Care of the</i>)	Marianne B. Bowler
<i>Florida Keys, Inc., et al. v. Dey, Inc., et al.,</i>)	
Civil Action No. 05-11084-PBS)	
)	

**DEY DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION
TO THE UNITED STATES' MOTION TO BIFURCATE**

PRELIMINARY STATEMENT

Defendants Dey, Inc., Dey Pharma, L.P., (formerly Dey, L.P.) and Dey L.P., Inc. (collectively, “Dey”) submit this memorandum of law in opposition to Plaintiff United States and Plaintiff-Relator Ven-A-Care of the Florida Keys, Inc.’s (collectively, “Plaintiffs”) motion to bifurcate.

Plaintiffs’ proposed bifurcation plan would violate Dey’s Seventh Amendment rights. Given the substantial factual overlap between Plaintiffs’ Medicare and Medicaid claims, trying Plaintiffs’ Medicare and Medicaid claims in two separate trials would result in two separate juries considering many of the same factual issues, including the key common issues of Dey’s knowledge and scienter, and thus could lead to inconsistent verdicts. The Seventh Amendment guarantees Dey the right to have the United States’ Medicare and Medicaid claims considered by a single jury.

Plaintiffs’ proposed bifurcation plan also does not accomplish the goals of Rule 42(b) of the Federal Rules of Civil Procedure. Bifurcating the Medicaid and Medicare claims

will not simplify the case or economize judicial resources, as Plaintiffs claim. Bifurcation creates a substantial likelihood of two, not one, lengthy and complex trials, with needless review of the same issues, exhibits, and witnesses by two separate juries. Indeed, Plaintiffs assert in their briefing that they intend to introduce Dey evidence specific to Medicaid in their proposed Medicare-only trial. This is hardly consistent with Plaintiffs' assertion that bifurcation will simplify the issues going to the jury.

Finally, Plaintiffs have not identified any unfair prejudice they will suffer if their claims are not severed. By contrast, Dey will be prejudiced if Plaintiffs are allowed to proceed on the bifurcation plan they propose. Plaintiffs apparently see bifurcation as a means of hiding fundamental weaknesses of their Medicaid claims from the jury, while at the same time presenting evidence of Dey's conduct that could only be relevant to Medicaid in their proposed Medicare-only trial. Rule 42(b) serves to promote just and efficient resolution of cases, not to serve the litigation strategies of one particular party. Plaintiffs chose to bring their Medicare and Medicaid claims in a single action, and should not now be allowed to use Rule 42(b) to cherry-pick their preferred claims for trial, and leave their lesser claims for another day.

ARGUMENT

I. BIFURCATION WOULD VIOLATE DEY'S SEVENTH AMENDMENT RIGHTS AND CREATE A SUBSTANTIAL RISK OF INCONSISTENT VERDICTS

Bifurcation of this action into separate Medicare and Medicaid trials would violate Dey's Seventh Amendment rights because it will result in multiple juries considering the same factual issues. Federal Rule of Civil Procedure 42(b) explicitly conditions the separation of trials on the preservation of litigants' right to a jury trial under the Seventh Amendment. Fed. R. Civ. P. 42(b) ("When ordering a separate trial, the court must preserve any federal right to a jury trial"). Dey is entitled to a jury trial for claims brought by the government under the Federal

False Claims Act because, among other things, Plaintiffs are seeking to recover civil penalties.

See United States v. Tri-State Hosp. Supply Corp., 23 C.I.T. 736, 748 (Ct. Int'l Trade 1999) (citing *Tull v. United States*, in which “the Supreme Court made clear that a civil penalty suit brought by the government is [an action] for which the Seventh Amendment preserves a defendant’s right to a jury trial.” 481 U.S. 412, 418-19 (U.S. 1987)); *see also United States ex rel. Rodriguez v. Weekly Publications, Inc.*, 9 F.R.D. 179, 181 (S.D.N.Y. 1949). The Seventh Amendment states that “no fact tried by a jury, shall be otherwise reexamined in any court of the United States, than according to the rules of the common law.” U.S. Const. Amend. VII. “Bifurcation violates the Seventh Amendment if a court divides issues between separate trials in such a way that the same issue is reexamined by different juries.” *Hoover v. Florida Hydro, Inc.*, 2009 U.S. Dist. LEXIS 68928, at *8 (E. D. La. 2009) (citing *Matter of Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1303 (7th Cir. 1995)); *see also Franchi Constr. Co., Inc. v. Combined Ins. Co. of Am.*, 580 F.2d 1, 7-8 (1st Cir. 1978) (vacating judgment where the trial court allowed non-distinct issues to be considered at a second trial under Federal Rule of Civil Procedure 42(b)).

For instance, in *Ingles v. City of New York*, No. 01-8279 (DC), 2005 WL 1354028, *1 (S.D.N.Y. June 7, 2005), the court denied a defendant municipality’s motion to bifurcate claims against it and several individual corrections officers brought by 22 prisoners alleging the use of excessive force. Even though the claims arose from 22 separate incidents, the plaintiffs’ claims “implicate[d] common issues, such as jail operations, use of force policies, and the standards for evaluating the reasonableness of force.” *Id.* Given the commonality of issues between the claims, the court concluded that bifurcation would violate the Seventh Amendment:

If twenty-two different juries are asked to decide the facts of each of the twenty-two different incidents in question, and twenty-two different juries are asked to decide the existence of a policy or practice of unconstitutional conduct, there is a risk of inconsistent

verdicts and the likelihood that a second jury would re-visit facts decided by a prior jury, in violation of the Seventh Amendment.

Id.; see also Manual for Complex Litigation (Fourth) § 11.632 (2005) (“[I]ssues for trial should not be severed if they are so intertwined that they cannot fairly be adjudicated in isolation, or when severance would create a risk of inconsistent adjudication.”)

Plaintiffs’ proposed bifurcation plan violates the Seventh Amendment for the same reasons that barred bifurcation in *Ingles*. A central element of Plaintiffs’ Medicare and Medicaid FCA claims is Dey’s *scienter* and, as their pleadings demonstrate, Plaintiffs see no distinction for Dey’s *scienter* as it relates to Medicaid as opposed to Medicare. *See* United States’ First Amended Complaint (“Amended Compl.”) at ¶ 4 (alleging that “...Dey knew that its false price reporting and marketing efforts would cause its customers to submit claims for fraudulently inflated Medicare and Medicaid reimbursement.”). Indeed, Plaintiffs intend to introduce evidence regarding Dey drugs reimbursed by Medicaid even in a Medicare-only trial for the purposes of demonstrating *scienter*. Without conceding that Plaintiffs would be allowed to do so, Dey notes that Plaintiffs’ own briefing on this motion states: “In a Medicare trial, the plaintiffs would expect to introduce some evidence concerning defendants’ other drugs (reimbursed by Medicaid) to show motive, intent, and plan ...” Memorandum in Support of Plaintiffs’ Motion to Bifurcate Medicare and Medicaid Claims (Docket No. 7047) (“Plaintiffs’ Memo”), at p. 5, n. 4. Moreover, Plaintiffs make no distinction between their Medicaid and Medicare claims regarding other aspects of Dey’s conduct. *See* Amended Compl. at ¶ 3 (alleging that “Dey reported false... drug prices for certain drugs ... to several price reporting compendia that Medicare and Medicaid programs relied upon...”); ¶61 (alleging that “[a]s a result of Dey’s conduct, pharmacists and other providers submitted thousands of claims to the Medicare and Medicaid programs and received ... excessive reimbursement.”). Plaintiffs have

pled Medicaid and Medicare claims stemming from a common course of conduct by Dey. Allowing the claims to go to two separate juries may lead to inconsistent verdicts and would violate Dey's Seventh Amendment rights.

II. BIFURCATION IS NOT PROPER UNDER RULE 42(B)

Plaintiffs' proposed bifurcation is not proper under Federal Rule of Civil Procedure 42(b). Rule 42(b) allows the Court to order separate trials on separate claims or issues “[f]or convenience, to avoid prejudice, or to expedite and economize.” Fed. R. Civ. P. 42(b). As the moving party, Plaintiffs bear the burden of demonstrating that bifurcation is justified. *See Cordero v. AT&T*, 190 F.R.D. 26, 29 (D. P.R. 1999) (“The moving party bears the burden of proving that separate trials are justified.”) Bifurcation of issues for trial is the exception, not the norm. *Data General Corp. v. Grumman Sys. Support. Corp.*, 795 F. Supp. 501, 503 (D. Mass. 1992) (“[S]eparation is not to be routinely ordered.”) Courts should consider the following factors when assessing whether to direct separate trials:

- (1) whether separate trials will help to simplify the issues and avoid confusion; (2) whether separate trials will result in duplication of evidence; (3) whether separate trials will create a risk of inconsistent verdicts; (4) whether separate trials will result in an efficient use of judicial resources; (5) whether separate trials will expedite or delay the proceedings; and (6) the effect on the parties' rights to a jury trial.

Commonwealth Land Title Ins. Co. v. IDC Prop. Inc., 482 F. Supp. 2d 203, 206 (D. R.I. 2007).

Plaintiffs have failed to demonstrate that any of these factors weighs in favor of bifurcation.

A. Bifurcation Will Result in the Duplication of Evidence and Will Not Alleviate Juror Confusion

Plaintiffs claim that bifurcation will avoid juror confusion by eliminating the introduction of Medicaid evidence at a Medicare-only trial is simply not true for two reasons: (1) extensive evidence concerning the federal government, which administers the Medicare

program and oversees the state Medicaid programs, will be relevant to both trials; and (2) Plaintiffs claim no distinction between Dey's conduct and intent as it relates to Medicare and Medicaid, and apparently intend to introduce the same Dey-specific evidence at a Medicaid and Medicare trial.

Plaintiffs' brief ignores the fact that the same federal agency, the United States Department of Health and Human Services, through the Centers for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration) ("CMS"), is responsible for administering both the Medicare and Medicaid programs. In particular, throughout the relevant time period, CMS administered the Medicare drug benefit, set policies governing state Medicaid drug reimbursement methodologies, approved individual state reimbursement methodologies, and received the AMPs Dey reported as part of the Medicaid rebate program. The Department of Health and Human Services' Office of Inspector General ("HHS-OIG") has issued a number of reports during the relevant time period comparing both Medicare and Medicaid reimbursement payments to providers' actual costs for drugs, including reports specific to the inhalation drugs at issue, albuterol sulfate, cromolyn sodium, and ipratropium bromide.¹ Evidence concerning CMS's policy decisions and HHS-OIG's investigations would be equally relevant in both a Medicare trial and a Medicaid trial, as would evidence concerning reimbursement formulae employed by state Medicaid programs.

For instance, from the start of the relevant time period through 1997, regulations promulgated by CMS required the Medicare program to use an undiscounted AWP as one possible reimbursement basis for drugs. During that same time period, CMS refused to approve amendments to state Medicaid plans that calculated pharmacy reimbursement based on an

¹ Plaintiffs' proposed bifurcation plan would limit the Medicare-only trial to claims related to ipratropium bromide and albuterol sulfate. *See* Plaintiffs' Memo at 2.

undiscounted AWP. If Plaintiffs intend to argue to the jury at a Medicare-only trial that AWP “refers to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail Customer who then administers it to a patient,” (Amended Compl. at ¶ 40), then Dey must be permitted to present evidence of CMS’s policy regarding Medicaid reimbursement formulae, as well as details concerning the Medicaid reimbursement formulae it approved. CMS is a single entity, and Plaintiffs should not be allowed to use bifurcation so that two different juries will hear incomplete evidence concerning its actions.²

Moreover, Plaintiffs admit that at a Medicare-only trial, they would still seek to introduce evidence of Dey’s practices relating to drugs reimbursed under the Medicaid program, but not the Medicare program, “to show [Dey’s] motive, intent, and plan ...” Plaintiffs’ Memo at p. 5, n. 4. Indeed, Plaintiffs’ proposed exhibit list contains several Dey documents that would have no direct relevance to Plaintiffs’ Medicare claims. For instance, much of the evidence on Plaintiffs’ proposed exhibit list appears to be offered to support Plaintiffs’ contention that Dey “marketed the spread” for its drugs; that is, promoted its drugs based on the margin a provider

² Plaintiffs suggest that the Court’s prior ruling regarding the “plain meaning” of AWP in the consolidated class action cases should limit the scope of evidence at a Medicare-only trial. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277 (D. Mass. 2006). The factual record and underlying legal issues in this False Claims Act case are completely different from those in the consolidated class action. That decision was reached in an action brought under the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A, §1 et seq. (the “Massachusetts CPA”) on behalf of consumers and private third-party payors and liability was premised on whether the defendants’ practice of reporting AWPs that exceeded a purported industry-expected 30 percent spread for brand drugs was “unfair or deceptive”. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 46-50, 82, 97 (D. Mass. 2007). By contrast, the relevant question in this action is whether Dey knowingly submitted or caused the submission of false claims for its generic drugs to the United States. Moreover, unlike the consolidated class actions, in this case there is an extensive evidentiary record concerning the United States’ understanding of generic pricing points and the specific policies behind the pharmacy reimbursement formulae it adopted or approved. Even assuming that the Court’s “plain meaning” definition of AWP were applicable in this case from 1998 on, the jury in a Medicare-only trial would still have to weigh this evidentiary record to determine whether Dey’s reported compendia prices caused any provider to submit a false claim, and whether Dey, in the context of the generic drug market, acted with the requisite *scienter*.

would receive between the actual acquisition cost for the drug and a third-party payor's reimbursement payment. *See* Amended Compl. at ¶ 3.

Evidence of "marketing the spread" is of marginal use in a Medicare-only trial, as "marketing the spread" is simply not feasible in the Medicare context. During the relevant time period, the Medicare program calculated reimbursement payments for generic drugs like the Dey drugs at issue in this action based on the median AWP for all generic versions of the drug. Thus, no single drug manufacturer could "inflate" its AWP to create a more attractive reimbursement "spread" than its competitors, much less use such a "spread" as a marketing tool to induce Medicare providers to purchase its drugs, since all Medicare providers were paid the same allowed amount regardless of the manufacturer of the drug dispensed by the provider. In contrast, under Medicaid, claims were reimbursement for a particular manufacturer's drug based on that manufacturer's specific NDC. If Plaintiffs are permitted to introduce "spread marketing" evidence and other evidence concerning Dey's conduct that relates to Medicaid, there are no efficiencies from bifurcating a trial.

B. Bifurcation Will Needlessly Tie Up Judicial Resources and Unnecessarily Delay the Resolution of This Case

Plaintiffs' bifurcation plan will not create any efficiency or otherwise speed up the resolution of this case. Rather, bifurcation will merely turn one complex trial into two complex trials with overlapping proof. Many of the same fact witnesses and all of the same expert witnesses will be called at both trials. As discussed above, much of the evidence from the first trial will need to be presented at the second trial. The jury at the second trial will have to grapple with many of the same issues put to the jury at the first trial, notably whether a reimbursement claim submitted by a provider that the government chose to pay based on a benchmark it knew did not reflect a provider's actual cost is a "false claim" under the False Claims Act, whether

Dey's reporting of prices caused the submission of false claims, and whether Dey had the requisite scienter under the FCA in light of Dey's price reporting practices, Dey's disclosures concerning its prices, and the extensive public record that the benchmarks at issue did not reflect providers' actual final net costs. Indeed, the only substantive difference between the first trial and the second trial would be that the jury would hear additional evidence concerning the individual state Medicaid programs. Separating one complicated case into two separate complicated trials will needlessly tie up the Court's resources and delay the ultimate resolution of this action.

Plaintiffs have not identified any real efficiency that would result from the bifurcation they propose. Unlike the bifurcation of liability and damages in a tort case – where a finding for a defendant at the liability trial precludes the need for the second trial altogether – Plaintiffs have failed to identify a single issue that, if resolved in a Medicare-only trial, would obviate the need for a Medicaid trial, or substantially reduce the length or scope of such a trial. Instead, Plaintiffs speculate that a verdict on their Medicare claims will prompt settlement of the Medicaid claims. If, in fact, the Medicaid claims settled following a verdict on the Medicare claims, there would be some economy realized. However, if the Medicaid claims do not settle, the Court would have to conduct a Medicaid trial that would entail overlapping evidence and issues, compounding rather than reducing the time and resources expended on this action. Courts do not accept bifurcation plans where economy results only from one possible outcome, and the other possible outcome would result in an unnecessary waste of time and resources. *See Fall v. Ind. Univ. Bd.*, 33 F. Supp. 2d 729, 738 (N.D. Ind., 1998) (denying bifurcation where “the benefits of bifurcation are dependent upon only one party prevailing in the first phase” and “a

marked and unnecessary waste of time and resources would occur in the second phase if the opposing party prevailed in the first phase”).

III. PLAINTIFFS CANNOT USE BIFURCATION TO CHERRY-PICK PORTIONS OF THE CASE AT THE EXPENSE OF DEY'S RIGHT TO A FAIR TRIAL

Plaintiffs complain that proceeding on a joint Medicaid/Medicare trial will require them to depose employees of state Medicaid programs that Dey has identified as potential witnesses in advance of trial or, alternatively, subpoena those witnesses for trial. Plaintiffs claim this is necessary because “[a] large number of the deposition transcripts designated by Dey were of depositions from state litigation where the United States was not a party and so was not cross-noticed (indeed, some of the depositions occurred before the United States even intervened in the three *qui tam* cases), and therefore had no opportunity to cross-examine.” *See* Plaintiffs’ Memo at 7. However, Plaintiffs cannot claim that they will be unfairly prejudiced if bifurcation is not granted, as they are the architects of this lawsuit and had the opportunity to pursue these depositions during discovery, but chose not to. More importantly, Dey will be unfairly prejudiced if Plaintiffs are allowed to try this case in the piecemeal fashion they propose as it will deprive Dey of the opportunity to put forth an adequate defense. “Perhaps the most important consideration for a court ruling on a motion to bifurcate is whether separate trials would unduly prejudice the non-moving party.” *Willemijn Houdstermaatschaapij BV v. Apollo Computer*, 707 F. Supp. 1429, 1435 (D. Del. 1989).

Plaintiffs do not claim that they did not have sufficient notice that it would be necessary to develop this testimony during discovery, or that they did not have an adequate opportunity to do so, nor can they. It was Plaintiffs’ decision to bring both Medicaid and Medicare claims in this case and, as the Court recognized at the July 24, 2008 status conference, Plaintiffs must prove their Medicaid claims on a state-by-state basis. *See* Transcript of July 24,

2008 Status Conference at 14:13-15:8. Plaintiffs could have worked with Dey to ensure that the state Medicaid record in this case was fully developed, but did not. Instead, they sought to limit the number of state Medicaid depositions that could be taken. *See Memorandum in Support of Motion for Expedited Clarification of the Governing Case Management Orders* (Dkt. No. 5346) (arguing that the applicable case management orders limited Dey to one 30(b)(6) deposition per state).

Plaintiffs' real concern appears to be that, having reviewed Dey's pretrial disclosures, they now realize Dey intends to put forward a much stronger defense to their Medicaid claims than they originally anticipated and would like an opportunity to improve the Medicaid record before those claims proceed to trial. Indeed, a close reading of Plaintiffs' briefing reveals other weaknesses with their Medicaid claims that Plaintiffs seek to avoid through bifurcation. For instance, Plaintiffs note that there would be no need to address problems with Professor Duggan's Medicaid damages and that the presentation of evidence demonstrating that state Medicaid programs made informed decisions to use Dey's reported prices as reimbursement benchmarks to achieve certain policy goals "would be severely curtailed..." *See Plaintiffs' Memo at p. 5, n. 5, p. 6.* As their briefing demonstrates, Plaintiffs see bifurcation as way to shield the fundamental weaknesses of their Medicaid claims from a jury.

Yet at the same time, Plaintiffs intend to introduce evidence of Dey's conduct in a Medicare-only trial that, as discussed above, could only have relevance to the Medicaid program. In other words, they wish to try Dey's Medicaid-related conduct to a jury, while at the same time depriving Dey of an opportunity to defend the Medicaid claims. Rule 42(b) is not a vehicle to serve the strategic interests of a particular party, especially at the expense of a fair and just

resolution of the case. "It is the interest of efficient judicial administration that is to be controlling under [Rule 42(b)], rather than the wishes of the parties." 9A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 2388 (3d ed. 2008).

CONCLUSION

For the reasons set forth herein, Dey respectfully requests that the Court deny the Plaintiffs' motion to bifurcate and grant such other further relief as it sees fit.

Dated: April 27, 2010

Respectfully submitted,

KELLEY DRYE & WARREN LLP

By: /s/ Philip D. Robben

Paul F. Doyle, BBO # 133460
Sarah L. Reid (admitted *pro hac vice*)
William A. Escobar (admitted *pro hac vice*)
Neil Merkl (admitted *pro hac vice*)
Philip D. Robben (admitted *pro hac vice*)
101 Park Avenue
New York, NY 10178
(212) 808-7800 (telephone)
(212) 808-7897 (facsimile)

-and-

Martin F. Murphy, BBO #363250
Robert E. Toone, BBO #663249
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02210
(617) 832-1000 (telephone)
(617) 832-7000 (facsimile)

Attorneys for Defendants Dey Pharma, L.P., Dey L.P., Inc., and Dey, Inc.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on April 27, 2010, a copy to LexisNexis File and Serve for posting and notification to all parties.

By: /s/ Philip D. Robben
Philip D. Robben